UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,282	12/19/2001	Mark W. Bleyer	3433-333	5918

7590 04/19/2007

Woodard, Emhardt, Naughton, Moriarty and McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/025,282	BLEYER ET AL.	
	Examiner	Art Unit	
	Maria Leavitt	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-60 and 62-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-60 and 62-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 02, 2007, has been entered. Species restriction remains correct and active for the request for continued examination of the instant Application.

2. Status of claims. Claims 36-60 and 62-65 are pending. Claims 36, 43, 45, 49, 50, 54-56, 59, 60 and 62 have been amended and claims 63-65 have been added by amendment filed on 02-02-2007. Therefore, claims 36, 43, 45, 49, 50, 54-56, 59, 60, 62 and claims 63-65, drawn to an injectable chemotherapeutic composition for implantation in a patient and a radiopaque implantable biomaterial, comprising a the bioabsorbable biomaterial formed in the shape of a coil, are under current examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to arguments

Withdrawn rejections in response to Applicant arguments or amendments

Claim Rejections - 35 USC § 103

In view of applicant amendment to introduce the limitation "formed into the shape of a coil" , rejections of claims 45 and 53 under 35 USC § 103 as being unpatentable over Voytik-Harbin et al., et al., et al., (US Patent No. 6,444,229) in view of Stinson et al., (US 2004/0111149 A1), has been withdrawn.

4. Remaining rejections in response to Applicant arguments or amendments

35 U.S.C. 112, first paragraph, written description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54 –60, 62 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 54 –60, and 62 when given the broadest reasonable interpretation encompass a genus of unspecified radiopaque, implantable biomaterial devices comprising a bioabsorbable collagenous biomaterial including multiple collagenous strips bonded to one another. Such claimed embodiment as recited in claim 54, when read as a whole, does not find any written support from the as-filed specification. The specification describes that it is possible to shape

large surface area constructs by combining two or more tela submucosa segments (p. 2 l, lines 11-13). Additionally, it discloses the use of collagenous biomaterial 10 as and individual layer or multi-layer (p.9, paragraph 2).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that the Artisan can reasonably conclude that the inventor(s) had possession of the claimed invention. Such possession may be demonstrated by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and/or formulae that fully set forth the claimed invention. Possession may be shown by an actual reduction to practice, showing that the invention was "ready for patenting", or by describing distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention (January 5, 2001 Fed. Reg., Vol. 66, No. 4, pp. 1099-11).

Applicant, provides only one example wherein a plurality of tela submucosa strips can be, fused to one another, by compressing overlapping area of the strips under dehydrating conditions, to form an overall planar constructs having a surface area greater than that of any one planar surface of the individual strips used to shape the construct. Additionally, a radiopaque powder can be disposed within these strips (p.21, paragraph 2). Further, Applicant discloses that shapes can be made by using sutures, staples, and biocompatible adhesives such as collagen binding paste or dehydrating overlapping structures. However, no other specific teachings on a number of other species of a of bioabsorbable collagenous material that are bonded to one another are disclosed other that the submucosa layer comprised in biomaterial 10. Moreover, the specification teaches in Fig. 1, a cross section of small intestine with the collagenous biomaterial

10 containing a multilayered device, comprising the following layers: tunica submucosa 46, lamina muscularis mucosa 47, from where the tela submucosa can be further delaminated. However, Applicant only states that the collagenous biomaterial 10 can be an individual layer or a multilayer, without any further directions about how these multi-layers can be bonded to one another.

This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of a radiopaque, implantable biomedical device, comprising a bioabsorbable collagenous biomaterial including multiple collagenous strips bonded to one another in any manner to promote remodeling of tissue of the patient at a site at which said collagenous biomaterial is implanted, at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

Reply to applicant arguments as they relate to rejection of Claims 54 –60, 62, under 35 U.S.C. 112, first paragraph, written description

On page 8 of Remarks, Applicants argue that "claim 54 as amended and its dependent claims require the use of collagenous strips that comprise tunica submucosa tissue" and as such, it is believed that the claims overcome the written description rejection under U.S.C. 112, first paragraph. Such is not persuasive.

Though the source of the bioabsorbable biomaterial such as strips comprising tunica submucosa tissue is disclosed in the as-filed specification, Applicant has not properly addressed the grounds of rejection as stated in the previous office action mailed on 11-28-2005. Applicant does not provide sufficient guidance to demonstrate that he is in possession of any variety of

suitable bonding techniques and materials as embraced by the invention and set forth and claimed.

35 U.S.C. 112, first paragraph, scope of enablement

Claims 54 –60, and 62 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claims 54 –60 and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for:

An implantable medical device, comprising;

A multi-strip bioabsorbable collagenous based submucosa, wherein a radiopaque marker is disposed in between collagenous layer segments of said multi-strip bioabsorbable collagenous based submucosa to promote remodeling of tissue of the patient at a site at which said bioabsorbable collagenous based submucosa is implanted,

does not reasonably provide enablement for a radiopaque, implantable biomaterial device, wherein multiple collagenous strips are bonded to one another in any mode to form a functional multilayer structure to yield results contemplated by Applicant

Reply to applicant arguments as they relate to rejection of Claims 54 –60, 62, under 35 U.S.C. 112, first paragraph, scope of enablement

On page 8 of Remarks, Applicants argue that "claim 54 has been amended in a fashion similar to the language suggested as enabled by the Examiner" and as such, it is believed that the claims overcome the enablement rejection under U.S.C. 112, first paragraph. Such is not persuasive.

As discussed above, and for the reasons of record, the disclosure provided by the applicant is not fully enabled for the scope embraced by the claims because applicant does not provide sufficient guidance to demonstrate how to make and use a variety of suitable bonding techniques and materials as embraced by the invention and set forth in the claims. The claimed invention as a whole required critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. The disclosure provided by Applicant must encompass a wide area of knowledge to enable one of ordinary skill in the art at the time the invention was made to practice the invention without undue experimentation.

Reply to applicant arguments as they relate to rejection of Claims 54 –60 and 62 under 35 U.S.C. 112, first paragraph, scope of enablement.

On page 8 of Applicant remarks, applicants argue that independent "claim 54 has been amended in a fashion similar to the language suggested as enabled by the Examiner" and, as such, reconsideration and withdrawal of this rejection is solicited. Such is not persuasive.

Though claim 54 has been amended, it is still broadly interpreted as a radiopaque, implantable device, comprising multiple collagenous strips that are bonded to one another in any mode to form a functional multilayer structure to yield results contemplated by Applicant. As

discussed above, and for the reasons of record, the disclosure provided by the applicant is not fully enabled for the scope embraced by the claims because applicant does not provide sufficient guidance to make and use a variety of suitable bonding techniques and materials as embraced and set forth by the invention in light of the guidance provided in the specification and knowledge available to one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

Claims 36-44 remain rejected under 35 USC § 103 as being unpatentable over Voytik-Harbin et al., et al., et al., (US Patent No. 6,444,229) in view of Stinson et al., (US 2004/0111149 A1) for the reasons of record.

Reply to applicant arguments as they relate to rejection of Claims 36-44 under - 35 USC § 103.

On page 9 of applicant remarks, Applicant argues that claims 36-45 and 53 now required that " bioabsorbable collagenous biomaterial provided in an injectable viscous gelatin suspension" in the claimed combination. Moreover, applicant contends that claims 45 and 53 now require "a bioabsorbable collagenous biomaterial formed into the shape of a coil, said bioabsorbable collagenous biomaterial effective to promote remodeling of tissue of the patient at a site at which said collagenous biomaterial is implanted, said bioabsorbable collagenous biomaterial including at least one biotropic agent selected from the group consisting of a proteoglycan, a growth factor, a glycoprotein, and a glycosaminoglycan" and that Neither

Voytik-Harbin nor Stinson, nor their combination, suggests this claimed combination". Such is not persuasive.

In relation to the new limitation "an injectable viscous gelatin suspension", the as-filed specification teaches on p. 19, lines that the comminuted tela submucosa 12 can be hydrated to form a fluid tissue graft composition and that the higher graft compositions can have a gel or paste consistency. Moreover, on p. 28, lines 4-9, the specification teaches that "due to the viscosity of the gelatin suspension, the invention 5 when injected into the lumen of an aneurysm, will stay in the lumen and provide the therapeutic benefit to the aneurysm". No other teachings are disclosed in relation to a "viscous gelatin suspension" as instantly claimed. Thus amended claim 36 is broadly interpreted as any collagenous biomaterial such as gels, pastes, gelatin that implicitly "resist internal flow by releasing counteracting forces" (e.g., definition of viscosity according to Webster's seventh new collegiate dictionary).The Voytik-Harbin patent discloses "the shape retaining gels of the present invention are translucent, having an optical density ranging from about 0.1 to about 2.0 at A405 nm" (col. 8, lines 41-45). See also column 10, lines 1-22, for teachings of the injectable therapeutic composition wherein "the injected material then gels at the in vivo site of injection thus immobilizing the composition at the injection site" (col. 10, lines 12-13). Hence Voytik-Harbin supplemented with Stinson, teach the claimed combination.

Claims 45-53 remain rejected and new claims 63-65 are rejected 35 USC § 103 as being unpatentable over any of Kropp (Urology, 1995), Whitson (US patent No. 5,997,575) and

Bonadio (US patent No. 5,942,496) each of them take with Stinson et al., (US 2004/0111149 A1) for the reason explained above and of record.

Claims 45-53 remain rejected and new claims 63-65 are rejected under 35 USC § 103 as being unpatentable over any of Badylak et al., (WO 96/24661), Badylak 2 (WO 96/25179), Cook et al., (WO 98/22158), Fearnot (US 6,358,284), Badylak 3 (US 2004/0078076) each of them take with Stinson et al., (US 2004/0111149 A1) for the reason explained above and of record.

Reply to applicant arguments as they relate to rejection of Claims 45-53 and 63-65 under - 35 USC § 103.

On page 9 of applicant remarks, Applicant agues that due to the amendment to claim 45, each of the claims 45-53 and 63-65 now requires "a bioabsorbable collagenous biomaterial formed into the shape of a coil, said bioabsorbable collagenous biomaterial effective to promote remodeling of tissue of the patient at a site at which said collagenous biomaterial is implanted, said bioabsorbable collagenous biomaterial including at least one biotropic agent selected from the group consisting of a proteoglycan, a growth factor, a glycoprotein, and a glycosaminoglycan" in the claimed combination. Neither of the reference combinations identified in the Office Action suggests such a claimed combination. Therefore, withdrawal of these rejections is solicited.

In relation to the new limitation of claim 45 reciting, "bioabsorbable collagenous biomaterial formed into the shape of a coil" as stated in the previous office action, each of the cited references teaches a variety of shapes, for example Whitson, US Patent 5,997,575 teaches

"flat plates but they can also include other shapes such as screens, opposed cylinders or rollers and complementary nonplanar surfaces" (col. 6, lines 5-10) or "hollow sphere or pouch ", (col. 7, line 22), it would have been obvious for one of ordinary skill in the art as a matter of design of choice to construct the biomaterial in any shape known in the prior art so long as the shape of the biocompatible material is compatible with an instrument used in the medical art of grafting for assisting with the placement of the biomaterial within the body of a grafted subject, particularly since shaping or molding techniques including sutures, staples, biocompatible adhesives are well-known in the prior art of record.

Moreover, with regards to the collagenous biomaterial Voytik-Harbin teaches that the submucosa can be prepared from delaminated warm-blooded vertebrate submucosa and can be digested to produce a hydrolysate that can be further dialyzed resulting in particles of less than 3500 MW (col. 9, lines 19-40). Further, Voytik-Harbin patent discloses that the vertebrate submucosa can be obtained from various sources, including intestinal tissue harvested from animals pigs (col. 2, line 63). Hence Kropp (Urology, 1995), Whitson (US patent No. 5,997,575) and Bonadio (US patent No. 5,942,496) each of them take with Stinson teach the claimed combination.

Conclusion

Applicant response filed on 02-02-2007 has been considered by the Examiner but is moot in view of the new grounds of the rejection, which is necessitated by the claims amendment.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Maria Leavitt, PhD
Patent Examiner P/1633
Remsen 2B55
Phone: 571-272-1085

AU 1633